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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/668,274

09/24/2003

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26486

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10/03/2007

EXAMINER

MACNEILL, ELIZABETH

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,274

Applicant(s)

WOLFF ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20, 25-45, 47 and 52-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 25-45, 47 and 52-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-3, 18,20,25-30, 45, 47, 52-54 rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (US 5,090,903) in view of Sakuma et al (US 5,584,688)

Taylor teaches an oral device for controlled drug release with at least one reservoir (21-23) and an oral anchoring mechanism of a bridge (11, Fig 1).

Taylor does not teach an electronic release mechanism.

Sakuma teaches an oral infusion device with a micropump (13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the micropump of Sakuma with the dental bridge of Taylor in order to more effectively control and adjust the release of the drug.

3. Claims 17,44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor/Sakuma in further view of Child (US 4,252,525).

Taylor/Sakuma teaches the limitations of the claims as above, but fails to teach that there is a component which increases drug transfer through a biological barrier, such as iontophoresis. Child teaches the use of iontophoresis in an oral implant (Fig 10). It would have been obvious to one of ordinary skill in the art at the time the invention was

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made to use iontophoresis with the implant of Sakuma in order to improve drug absorption.

4. Claims 4-16, 31-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor/Sakura in further view of Pfeller et al (US 5,558,640) and Voyiazis et al (US 2004/0147906).

Taylor/Sakura teaches the limitations of the claims as above, but fails to teach the use of a sensing component and a telemetry communication component. Pfeller teaches an implantable infusion device with a condition and/or status sensor (2), a processor with timer (4), and a telemetry communication unit (8,12,16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the telemetry and sensor controls of Pfeller in order to provide an additional means to control and communicate with the oral device. Furthermore, Voyiazis teaches these same elements within an oral device. At the time the invention was made, it was well known in the art to use these control means in an oral implant.

Response to Arguments

5. Applicant's arguments with respect to claims 1-18, 20, 25-45, 47 and 52-54 have been considered but are not persuasive. Regarding Taylor in view of Sakura as applied to claims 1-3, 18,20,25-30, 45, 47, 52-54, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The combination of the two references teaches all of

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the claimed limitations. See Sakura Fig 11 and Col 7-8. The term "micropump" in combination with the description of the pump would necessitate that the pump includes the claimed limitations, such as the electronics and power source. See also Voyiazis. In response to applicant's arguments regarding Child and Voyiazis, it is taught that the device may interact with the skin of the patient's mouth. The examiner interprets this to mean that the special environment, to the extent that it exists, in the mouth has been taken into account and is capable of functioning as a non-implanted, but secured, dental piece. Taylor teaches the limitations of the secured dental piece which is used to deliver medication to the mouth. Therefore, the combination of these references is appropriate.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

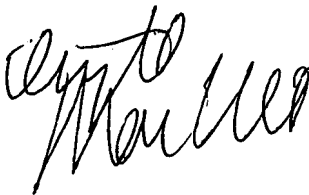
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

